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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,732	07/25/2001	Joseph Atabekov	0933-0169P	5590
2292	7590	07/06/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				LAMBERTSON, DAVID A
ART UNIT		PAPER NUMBER		
				1636

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/911,732	ATABEKOV ET AL.
	Examiner	Art Unit
	David A. Lambertson	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19,20,23,24,29-31,33,34,36,38 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) 19,23,24,29-31,33,34,40 and 44 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20,36,38,41-43 and 45-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed April 16, 2004.

Amendments were made to the claims. Specifically new claims 44-48 were added.

Acknowledgement is made of the Terminal Disclaimer filed April 16, 2004.

Claims 19, 20, 23, 24, 29-31, 33, 34, 36, 38 and 40-48 are pending in the instant application. Claims 19, 23, 24, 29-31, 33, 34, 40 and 44 are withdrawn from consideration. Claims 20, 36, 38, 41-43 and 45-48 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed January 16, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Election/Restrictions

Newly submitted claim 44 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: newly added claim 44 is directed to a method, as opposed to the originally presented product. Claim 44, has been withdrawn for substantially the same reasons as claims 19, 23, 24, 29-31, 33, 34 and 40 in the previous Office Action.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claim 44 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has traversed the alleged newly imposed restriction requirement wherein the process claims of 19, 23, 24, 29-31, 33, 34 and 40 were withdrawn from consideration. Applicant traverses, indicating that no reasons were given for the allegedly newly imposed restriction requirement.

It is noted that this was not a “newly imposed” restriction requirement. Applicant had previously received a restriction requirement with regard to the instant application, wherein said method claims were not elected for prosecution. Applicant then received a subsequent first Office Action on the merits whereby said method claims were also not examined. As such, the claims were not elected by original presentation. The previous Office Action makes clear this reason why the claims were withdrawn in a proper manner, pointing to the appropriate sections of the MPEP setting forth the guidelines for restriction. As such, Applicant’s traversal is not found convincing, and the restriction requirement is maintained.

The Office acknowledges the reference to MPEP § 821.04 with regard to the rejoinder of product and process claims upon the allowability of a product claim. It is also noted that the rejoinder shall occur upon the allowability of the product claim, wherein the process claims are commensurate in scope with the patentable product. Should the product claim become allowable, the process claims will be rejoined.

Information Disclosure Statement

The information disclosure statement filed April 16, 2004 has been considered, and a signed and initialed copy of the form PTO-1449 has been attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20, 36, 38, 41-43 and 45-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for the reasons set forth in the previous Office Action, and is now applied to newly added claims 45-48.**

Claims 20, 36, 38, 41-43 and 45-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an IRES of crTMV origin, does not reasonably provide enablement for any IRES element originating from any plant virus having a plus-sense single-stranded RNA genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This rejection is maintained for the**

reasons set forth in the previous Office Action, and is now applied to newly added claims 45-48.

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments with regard to the rejection under Written Description, filed April 16, 2004 have been fully considered but they are not persuasive. The following grounds of traversal are set forth:

1. The claims have been amended to contain a limitation wherein the plant-specific IRES originates from a plant virus having plus-strand single-stranded RNA genome. The contention is that this limitation satisfies the written description for the claimed invention because such viruses were generally known before the priority date of the instant application (see page 10-11, bridging paragraph of the response).
2. It is argued that the specification teaches the skilled artisan where to look for an IRES in plus-strand single-stranded RNA plant viruses (see page 11, first full paragraph of the response).
3. It is argued that the present invention is a fundamental invention, describing the first IRES sequences that are active in plants and plant cells, and that limiting the scope to tobamoviral IRES or even specific IRES of the examples does not provide adequate protection relative to the contribution of the inventors (see page 11, second full paragraph of the response).

These arguments are not found convincing for the following reasons:

1 and 2. The new limitation set forth in the claims also lacks sufficient Written Description for the same reasons set forth in the previous Office Action. There is no disclosure of a structure-function relationship for the IRES elements set forth in the claims such that the skilled artisan

can envision the broad genus of IRES elements originating from plus-strand single-stranded RNA plant viruses. The instant specification simply sets forth an IRES from crTMV; this is not a representative number of IRES elements sufficient to describe the broad genus of IRES elements from any plus-strand single-stranded RNA plant virus, nor is there a disclosed structural feature within the crTMV IRES that would allow the skilled artisan to envision other IRES elements from plus-strand single-stranded RNA plant viruses. The fact that the viruses were known at the time of the invention does not lend written description to the IRES elements contained within those viruses because the elements were not described.

The Written Description requirement involves the ability to envision the claimed invention. If an invention requires further identification, the invention cannot be described; this is unless there is a structural element to the invention that is indicative of the function of that element (i.e., a structure-function relationship for that element). However, as set forth above, there is no disclosure in the instant specification that says what structural feature of the IRES element is responsible for its function. The fact that these IRES elements can be found upstream of certain genes within a virus does nothing to describe the structure of the functional element itself. The instant argument simply demonstrates an invitation to identify new IRES elements that have not already been described, but which are functionally claimed. This is the antithesis of the Written Description requirement.

3. The fundamental nature of the invention is exactly why the Written Description requirement must be met. The fact that these are the first IRES elements that are active in plants and plant cells does not diminish the need to satisfy the Written Description, but rather accentuates the need for it. The limiting of the scope is based upon what is actually described in the

specification. In the instant specification, a particular IRES element is described without any indication of the structural requirements for its function; this does not entitle protection to the broad genus of IRES elements, especially when such IRES element may have a different structural element that is required for its function. In other words, the additional IRES elements to be used are completely unknown and cannot be envisioned.

The lack of description for the broad genus of IRES elements set forth in the claims is fully supported by a reference authored by a number of the instant inventors. As set forth in the previous Office Action, Ivanov *et al.* indicates that the crTMV is unique, even with respect to plant viruses within the same genus (see the previous Office Action, page 4-5, bridging paragraph). It is noteworthy that this statement is not addressed in any way in the traversal of the rejection. Thus, in Applicant's own opinion (Ivanov is one of the Applicants), the single IRES element that is described in the instant specification is unique onto itself, and not among plus-strand single-stranded RNA plant viruses. If the element is unique even among plant viruses within the same genus, it is impossible for this single example be representative of other IRES elements in those plant viruses (i.e., plus-strand single-stranded RNA plant viruses).

In conclusion, there is insufficient evidence in the arguments to overcome the instant rejection. Neither the narrowing of the limitations, the previous knowledge of the viruses (as opposed to the IRES elements contained therein), the ability to experimentally identify new IRES elements, nor the arguments that the scope of the claims is being unfairly narrowed is sufficient to overcome the evidence provided in Ivanov *et al.* The fact is that Applicant recognizes the uniqueness of the single IRES element described in the instant specification, even among plant viruses of the same genus. As such, the IRES cannot be representative of other

IRES elements originating from plant viruses of the same genus. Therefore, the rejection is maintained.

Applicant's arguments with regard to the Enablement rejection filed April 16, 2004 have been fully considered but they are not persuasive. The following grounds of traversal are set forth:

1. The claims have been amended to contain a limitation wherein the plant-specific IRES originates from a plant virus having plus-strand single-stranded RNA genome. The contention is that this limitation satisfies the enablement requirement for the claimed invention because such viruses were generally known before the priority date of the instant application (see page 13, second full paragraph of the response).
2. It is argued that the specification teaches the skilled artisan where to look for an IRES in plus-strand single-stranded RNA plant viruses (see page 13-14, bridging paragraph of the response).
3. It is argued that limiting the claims to IRES elements from plus-strand single-stranded RNA plant viruses allows the skilled artisan to easily identify the IRES elements that are used in the claimed invention (see for example page 14-15, bridging paragraph of the response).

The arguments are not persuasive for the following reasons:

1, 2 and 3. The amendment to the claims does not aid in the ability to make the invention as claimed. As set forth in the previous Office Action, Applicant's own publication (see Ivanov *et al.* as cited previously) clearly states that the crTMV IRES element set forth in the instant specification is unique even among plant viruses of the same genus (i.e., plus-strand single-

stranded RNA plant viruses). If the element is unique among these related viruses, the skilled artisan cannot make a completely unrelated functional element (i.e., an IRES from another plus-strand single-stranded RNA plant virus) based upon the disclosure of only the unique IRES sequence. The fact that these viruses were well known in the art prior to the instant application is not disputed; however, this prior art does not establish the nature of the functional elements within the viruses that are to be used in the instant claims. As such, the existence of the viruses is irrelevant to the instant rejection.

The argument that the IRES elements to be used in the claimed invention can be identified is also insufficient to overcome the issue of enablement. The instant arguments merely represent an invitation to experimentation; in the instant case the experimentation would be undue and unpredictable, especially based upon the uniqueness of the IRES element (again, see Ivanov *et al.*) that is actually disclosed in the instant specification. The standard of enablement is to make and use, not to identify; it is also well established that a patent is not a hunting license, drawn to allow the identification of the very nature of the invention. It is not possible to make something that is unknown, as is the instant case with IRES elements originating from plus-strand single-stranded RNA plant viruses. It is duly noted that statements in Ivanov *et al.* indicate that some of the related viruses do not even appear to have IRES elements (again see the Abstract and page 33, the first full paragraph). Indeed, the arguments point out that the functional element that defines the invention over the prior art must still be experimentally determined along the breadth of the claims as presented.

It is again noted that the arguments do not address the teachings of Ivanov *et al.*, which establishes the unique nature of the crTMV IRES element, even among viruses of the same

genus. Yet, even in the face of this teaching, it is still argued that this single unique element is representative of any IRES element originating from a plus-strand single-stranded RNA plant virus. If this is the case, it is not clear how the IRES element of crTMV can be considered unique, as set forth by the instant inventors in their own publication. Thus, the teachings of Ivanov *et al.* do provide evidence contradicting the enablement of the broad scope of the claims set forth in the instant application, in accordance with MPEP § 2164.04. Because no evidence obviating the teachings of Ivanov *et al.* have been provided, the enablement rejection is maintained.

Allowable Subject Matter

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1636



JAMES KETTER
PRIMARY EXAMINER